JAN 2 1 2004

K032511

510 (k) Summary of Safety and Effectiveness for Intuition Image

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
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Contact Person: Mr. Rainer Birkenbach

Summary Date: August 1, 2003

Device Name:

Trade name: Intuition Image

Common/Classification Name: Planning System/X-ray radiation therapy system

Predicate Device:
iPlan! (K020631)
BrainSCAN (K994413)

Device Classification Name: X-ray radiation therapy system
Regulatory Class: Class II

Intended Use:
Intuition Image's indications for use is to prepare and present patient and image data based on CT, MR, Angiographic and other imaging sources including

- image preparation
- image localization
- image fusion
- image segmentation
- isocenter handling
- plan review and approval

where the result is used for stereotactic radiation treatment planning that is intended for use in stereotactic, conformal, computer planned, LINAC based radiation treatment of cranial, head and neck and extracranial lesions.

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Device Description:
Intuition Image is a software tool running on a standard, standalone computer workstation or being accessible via the intranet connection for pre-planning of treatments based on stereotactic systems.

The system provides e.g. tools for the automatic or manual segmentation of anatomical structures, which helps the user such as the radiologist or the neurosurgeon to quickly achieve the desired segmentation results through a variety of automatic and/or manual re-segmentations. Additionally anatomical and functional structures and segmentations of the human brain as defined and described by Talairach/Tournoux and/or Schaltenbrand/Wahren brain atlases can be correlated with the patient's brain data.

The created treatment plans of Intuition Image can be used on its own or in conjunction with other BrainLAB treatment planning systems such as Intuition Dose (to be developed) or BrainSCAN (K994413) for further planning of parameters, which are relevant for Radiotherapy/Radiosurgery. Intuition Image may also serve as a pre-planning station for various third party treatment planning systems.

Substantial equivalence:
Intuition Image has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate devices iPlan! (K020631) and BrainSCAN (K994413).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstraβe 8
85551 Heimstetten
GERMANY

Re: K032511
Trade/Device Name: Intuition Image
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 LHN, and MUJ
Dated: December 5, 2003
Received: December 10, 2003

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032511

Device Name: Intuition Image

Indications For Use:

Intuition Image's indications for use is to prepare and present patient and image data based on CT, MR, Angiographic and other imaging sources including

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ______

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032511